

N.K.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

3

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,821	08/15/2001	Atsuo F. Fukunaga		2396

7590 02/20/2003

Daniel B. Schein, Ph.D., Esq.
BRINKS HOFER GILSON & LIONE
P. O. Box 10395
Chicago, IL 60610

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No. 09/930,821		Applicant(s) FUKUNAGA ET AL.	
Examiner Joseph Weiss		Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3761

DETAILED ACTION

1. Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The combination device of claim 21 was not previously presented. Furthermore, the devices of claims 13 & 18 were never previously set forth as being separate and distinct inventions usable together, but instead were presented as different embodiments of the same invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the filter located **in the proximal fitting** of claims 15 & 16 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

Art Unit: 3761

3. The amendment filed 4 Mar 02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: A proximal fitting with a filter located in one of its lumens as set forth in claims 15 & 16. Applicant must cancel the new matter in the reply to the Office Action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The use of a filter element within a lumen of a proximal fitting.

6. Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13 applicant repeats verbatim the preamble of claim 13 in the body of the claim, thus rendering the claim indefinite for the following reasons:

The redundancy of the preamble renders the claims indefinite because it is now unclear whether or not applicant is claiming one or two "multi-lumen proximal fittings," also it is unclear

Art Unit: 3761

how a proximal fitting can be comprised of itself, it is unclear if applicant's intended use/purpose language of the preamble is being used to further define the invention or not, because the intended use/purpose language is still being presented in the same manner.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 13-14 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Dryden (US 5284160).

In regards to claim 13, Dryden discloses a multi lumen proximal fitting, Fig 1, # 33, which is operatively connectable to a proximal terminal (41) and comprises a rigid housing (33A) having two independent lumens (inner lumen within 33b & outer lumen between 33b & 33a) having a proximal machine end (35A/B) and a distal patient/unilimb hose end (rim/flange that interfaces with the hose 27) wherein said fitting may be operatively connectable to a multi-lumen proximal terminal (See fig 3 interface with 41)(See col. 5 lines 32-40), this terminal having first and second ports at its distal end of third and forth lumens so that when the proximal ends of the first and second lumens of the of the fitting are operatively attach to the first and second ports they establish a flow path with the corresponding third and forth lumens of the proximal terminal such

Art Unit: 3761

that the flow paths defined by the lumens are independent wherein the fitting is fully capable of being operatively attachable to and detachable from a mating proximal terminal by a user at the site of use.

In regards to claim 14, discloses the lumens as being co-axial.

In regards to claim 17, Dryden discloses the lumens terminating in third and fourth distal ports and fifth and sixth proximal ports wherein the ports are co-axial.

In regards to claim 18, Dryden discloses a unilimb respiratory conduit (27/29) for artificial respiration, for use with a proximal terminal, such a terminal having lumens for ingress and egress of respiratory gasses in independent flow paths which are operatively independently connectable, (See col. 5 lines 32-40) the unilimb conduit comprising first and second lumens forming independent flow paths having a distal patient end and a proximal machine end, the distal end being operatively connectable/detachable to a patient by a user at the site of use (note interface 28A & 13B) and said proximal end of said conduit is operatively connectable/detachable from a proximal terminal by a user at the site of use (note the above rejection of claim 13), wherein when they are connected at the proximal terminal the first lumen is in fluid communication with inspiratory flow path (note arrows depicting flow of gas toward the patient end) and second lumen in fluid communication with the expiratory flow (note the arrows depicting flow to the machine) wherein the first lumen is operatively connectable to the inspiratory gas via the proximal terminal, while the second lumen is operatively connectable to the expiratory outlet via a proximal terminal wherein the respiratory conduit is fully capable of operatively attachable to and

Art Unit: 3761

detachable from a proximal terminal after use for independent disposal or sterilization (See col. 5 lines 32-40) by a user at the site of use.

In regards to claim 19, Dryden discloses a respiratory conduit interface device (33) capable of operative coupling to the unilimb, multi lumen, flexible respiratory conduit of the type described in claim 18, as noted in the above rejection to claim 18 which is herein incorporated by reference, to a respiratory device comprising a rigid housing (33A) with first and second lumens defining first and second independent flow paths and having a proximal (machine) end and a distal (patient) end and wherein said flow paths diverge from each other proximally of said distal end of said housing so that the proximal end of said first lumen is independently connectable to an inlet for a source of inspiratory gas (35B via 41B) while the proximal end of the second lumen is independently operatively connectable to an expiratory outlet, wherein the hose of claim 18 is operatively attachable to the housing for use and detachable for disposal/sterilization. (See col. 5 lines 32-40)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden.

Art Unit: 3761

In regards to claim 20, the reference noted above substantially disclose the claimed invention to include the respiratory conduit being operatively attachable and detachable (See col. 5 lines 32-40) but does not disclose the interface being “permanently” connected to a machine. It is noted that applicant’s specification does not set forth this “permanent” attachment, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary. (See *Fukunaga* 4265235)

11. Claims 15 & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dryden in view of Lorenzen (US 5715815).

In regards to both claims 15 & 16 Dryden substantially discloses the instant application’s claimed invention to include the use of a filter (12), but does not explicitly disclose the use of a filter in a lumen of the connector. However, Lorenzen disclose such (element 50). The references are analogous since they are from the same field of endeavor, the respiratory arts and the same problem solving area, the interconnection of multi-lumen apparatuses to a respiratory device. At the time the instant application’s invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Lorenzen and used them with the

Art Unit: 3761

device of Gross. The suggestion/motivation for doing so would have been to reduce the likelihood of pulmonary infection in a patient/user . Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

12. Applicant's arguments filed 26 Nov 02 have been fully considered but they are not persuasive.

In regards to applicant's assertions as to the content and nature of the interview in the bridging text on pages 4-5 of the instant amendment, applicant is in error. The content is only as reflected on the interview summary dated 14 Nov 02.

In regards to the objection to the drawings, applicant's amendment is proper and responsive but does not resolve the issue, applicant points to various filter housings disclosed by the application in the drawings and portions of the written description, none of which expressly and clearly set forth that a multi-lumened filter housing is a "proximal fitting." The only proximal fitting disclosure the application sets forth is in support of figs 14-19. This disclosure is devoid of there being any indwelling filter elements within the two lumens therein defined by a proximal fitting structure. Applicant needs to point to either an express teaching or a teaching that one of

Art Unit: 3761

ordinary skill in the relevant art would immediately appreciate a proximal fitting with two independent lumens that have filter elements retained within them at the time the application was filed, and not *ex post ad hoc* speculation as how the original filing can be stretched. Therefore the objection is retained. For these same reasons the objection to the specification is retained.

For these same reasons the rejections under 35 USC 112 regarding claims 15-16 is retained.

In regards to the rejections under 35 USC 112 regarding claims 13 & 19, the amendment is proper and responsive and resolves the issue, therefore the rejection is withdrawn.

Applicant's IDS submission falls short of being evidence that the swivel connector does not come on and off the device, it mere states other arrangements as to how respiratory circuits can be connected, not how a swivel connector can or cannot connect. Applicant has submitted no positive evidence as to how a swivel connector is attachable/detachable, hence it does not meet the guidance given to applicant in the interview.

In regards to applicant's assertion that the prior rejection was mere speculation, please note that the rejection used the statutes and binding CFRs of US title 35 and used objective analysis of the facts in application of the law.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Art Unit: 3761

Applicant's arguments do not comply with 37 CFR 1.111© because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

Applicant asserts the prior art teaches away, as clearly set forth by the rejection, the reference possesses all the structure of the instant application's invention, hence it is fully capable of performing all the intended use/result limitations that applicant stresses as being the differences applicant feels distinguish.

In regards to the inoperative state of the device of figure 1, applicant has not presented a judicial finding of non-enablement of the patent, hence applicant's attack of the presumption of validity of the prior art US patent is not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the proximal terminal, which is only set forth as part of the environment within which the invention is intended to operate and not positively claimed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The swivel empirically is attached to the proximal fitting and the illustrations show a septation in structure, therefore the two elements are separable, and fitted to each other. As a swivel there would be no bonding material at this interface because this would prevent movement

Art Unit: 3761

of the interface as a swivel. Someway, somewhere and somehow the two as separate elements were connected together, nothing in the reference says they cannot be disconnected. It is common knowledge that respiratory conduits are removed from respirators, and the entire systems are not discarded when switching from one patient to another. Snap fitting connections are also common knowledge in the art. Noting references US 6415789, 6209539, 4676241, all set forth in the relevant art the use of snap fit interfaces in the design and construction of a swivel joints as part of respiratory circuits, hence there is a reasonable basis to conclude that one of ordinary skill in the art would consider that the freely rotating swivel interface of two separate elements that are designed to be mated together would also be "un-matable" and hence fully capable of meeting this intended result/use purpose (non-structural) limitation.

Applicant's assertion that the relevant connection interface is bonded contrary to the plain language of the reference and rejection. It makes no sense to bond a swivel connection, as it goes against the very purpose of the swivel connection.

In regards to the remarks regarding the 103 combination rejection, for the same reasons noted above in regards to Dryden the argument is not persuasive and the rejection is retained.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6415789, 6209539, 4676539

Art Unit: 3761

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. If a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.


February 1, 2003


WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700